U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Coberg, Inc. 6/2/09

hhsbluebird Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612·2506

Telephone: 949-608-2900
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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 18-09

June 2, 2009
Mr. Ole Johanssen, Owner
Cobeg, Inc.
449 Kellogg Way
Unit B
Goleta, CA 93117

Dear Mr. Johanssen:

During an inspection of your firm located in Goleta, California, from December 2, 2008, through December 4, 2008, and from February 2, 2009, through February 4, 2009, an investigator from the United States Food and Drug Administration (FDA) determined that your film manufactures silicone facial implants that are identified in your product catalog that you provided to our investigator during the inspection. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are considered devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or function of the body.

These inspections revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, **Code of Federal Regulations** (CFR), Part 820. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures to adequately control environmental conditions that could be reasonably expected to have an adverse effect on product quality. Failure to periodically inspect environmental control system(s) to verify that the system is adequate and functioning properly, as required by 21 CFR 820.70(c).

For example:

a) Certification of the **(b) (4)** filtration system, used to control particulates in the environment during manufacturing processes, was not maintained to meet the Class 100 requirement per IS014644. This equipment was last certified on August 25,2003, and required recertification on August 25, 2004. There is no documentation that recertification has been performed.

b) The entrance to the production room was covered by plastic sheeting which does not provide an adequate barrier to prevent products from environmental contamination.

2. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a).

For example, your firm did not establish and maintain complaint handling procedures. You provided a complaint handling procedure during the February, 2009 inspection. This complaint handling procedure is deficient in that it does not meet the requirements under 21 CFR 820.198(a). The procedure does not discuss the process for receiving, reviewing, and evaluating complaints by a formally designated unit. The procedure does not ensure that all complaints are processed in a uniform and timely manner, that oral complaints are documented upon receipt, and that complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR part 803.

3. Failure to retain records required by the QS regulation (21 CFR part 820) for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer, as required by 21 CFR 820.180(b).

For example, you have stated that all device history records (DHR's) for devices produced after January 2000, were discarded **(b) (4)** As a

result, DHR's for the extended malar implants were not available for inspection. Under 21 CFR 820.184, you are required to maintain DHR's, which shall include, or refer to the location of, information such as: the dates of manufacture, the quantity manufactured, the quantity released for distribution, and the acceptance records which demonstrate the device is manufactured in accordance with the device master record (DMR). All records required by QS regulation must be retained for a period of time equivalent to the design and expected life of the device, but in no case less than two years from the date of release for commercial distribution. You sold and shipped extended malar implants in November 2008.

4. Failure to validate with a high degree of assurance and approve according to established procedures, a process where the results cannot be fully verified by subsequent inspection and test. Failure to document process validation activities and results, as required by 21 CFR 820.75(a).

For example, your firm did not validate the sterilization process referenced in the devices' Instructions for Use. Since the results of the sterilization process cannot be fully verified by subsequent inspection and test, the sterilization process must be validated with a high degree of assurance and approved according to established procedures. Your firm must document the validation activities and results. However, your film has no written sterilization studies to validate the effectiveness of the sterilization methods and cycles described in these devices' Instructions for Use.

5. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a).

For example, you lack procedures that analyze processes, work operations, concessions, quality audit records, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. You also lack procedures for investigating the cause of nonconformities relating to product, processes,and the quality system. Furthermore, you lack procedures for identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems.

Our inspection also revealed that your firm's devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that your firm failed or refused to furnish material or information respecting the devices that is required by or under section 519 of the Act, 21 U.S.C. 360i, and 21 C.F.R. 803 - Medical Device Reporting (MDR) regulation. Significant deviations include, but are not limited to, the following:

Failure to develop, maintain, and implement written MDR procedures, as required by 21 C.F.R 803.17. Specifically, your firm did not have any written procedures for identify, communicating, and evaluating events that may be subject to MDR requirements.

In addition, our inspection revealed that your devices are misbranded under section 502(0) the Act, 21 U.S.C. 352(0), in that the devices were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510, 21 U.S.C. 360; were not included in a list required by section 510(j), 21 U.S.C. 360(j); or a notice or other information respecting the devices was not provided to the FDA as required by section 510(k), 21 U.S.C. 360(k).

You should take prompt action to Correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Waming Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (IS) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to:

Dennis Farley
Acting Director, Compliance Branch
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2506

If you have any questions about the content of this letter please contact: Dr. William Vitale, Compliance Officer, at 949-608-2919.

Due to the fact that you did not maintain device history records for the silicone facial implants you manufacture, it is unclear whether your firm used expired **(b)(4)** in the manufacturing of these devices. If this is the case, to be compliant with 21 CFR 820.75(a), will need to provide a validation or stability study that demonstrates that **(b)(4)** with a "Use by" date of August 2, 2004, could be used for the manufacture of these products after this date and still meet finished product design specifications.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at yom facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring yom products into compliance.

Sincerely yours,

/S/

Alonza E. Cruse
District Director

Cc: Jeff Farrar, DVM, PhD, MPH
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